DECLARATION OF MICHAEL D. TRIPLETT, PH.D. UNDER 37 CFR 1.132

I, Michael D. Triplett, 5061 Cloudberry Pass, New Albany, Ohio 43054, United States of America, hereby declare the following:

- I am Director, Commercialization Health & Life Sciences global Business group of Battelle Memorial Institute, 505 King Avenue, Columbus, OH 43201 and have held this position since 2007;
- I have 4 years of direct experience in pharmaceutical product research; prior to that I was a product development engineer at a major consumer products company;
- I have B.Sc. in Chemical Engineering and a Ph.D. in Chemical Engineering Carnegie both from The Ohio State University;
- A comprehensive listing of my education, training, and accomplishments is set forth in my *Curriculum Vitae* attached as Annex A and incorporated in this Declaration;
- I have read the Advisory Action dated 11/02/2009 and particularly the portion that characterizes the disclosure of the Coffee reference ((WO 98/03267);
- I have read and understand the Coffee reference and especially the disclosure at page 31 of the reference;
- I have read and understand the disclosure of USSN 10/018,160 (the '160 application) and the claims filed in Applicant's Response filed September 21, 2009;
- It is my understanding that the broad invention claimed by the '160 application is a method of preparing a rapidly dissolving tablet that is formed using electric field technology ("EFET"), sometimes referred to as electrohydrodynamic ("EHD") aerosolization;
- As would be recognized by one skilled in the pharmaceutical formulation arts, the term "rapid dissolution" or "rapid release" drug product is not the same as a "controlled release" drug product;

- As would be recognized by one skilled in the art of pharmaceutical formulation, a "controlled-release" product is formulated to release the active agent gradually and predictably over a 12-hour to 24-hour period;

- The term "rapid release" (rapid dissolve) or "immediate release" refers to a drug product which has zero-order or first order release of the active agent from the product and which releases the active agent in seconds or minutes rather than hours;

- The major advantage of a rapid release or immediate release product is the relatively immediate availability of the active agent in the blood of the patient; rapid onset of the therapeutic effect of the active agent is particularly useful in such therapeutic categories as e.g., anti-diarrheas, anti-epileptics, anti-migraines, anti-coagulants, and the like;

- The Coffee reference at page 31, paragraph 1, describes a method which produces fibrils or particles which have a core of a biologically active agent e.g., drug; these particles or fibrils may in turn be added to a gelatin capsule, enabling, especially in the case of microcapsules, "good control" over the release of the drug;

- In my opinion based on my knowledge and experience, the term "good control" used by the Coffee reference refers to "controlled release" product; my opinion is based on my understanding of the polymers described in the Coffee reference as being useful in the wound dressings of the Coffee invention;

- The polymers used in the Coffee invention are:

Polyhydroxybutyric acid	Polyglycolic acid (PGA)
Polyvinyl alcohol	Polylactic acid (PLA)
New Skin®	Polyurethane

These polymers are known to be useful in the preparation of controlled release pharmaceutical products; PLA and PGA are known to be useful in the production of absorbable sutures; as would be commonly recognized, absorbable sutures absorb over a period of days not seconds or minutes (see *Medical Plastics & Biomaterials Magazine*, 1997 attached as Annex B);

- In my opinion, the disclosure of the Coffee reference at page 31 does not describe a rapid-dissolve drug product and thus, it does not the method of preparation of a rapid-dissolve tablet product claimed in USSN 10/018,160;

- I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: November 23, 2009 By: _____

Name: Michael D. Triplett, Ph.D.